
Plan Overview

A Data Management Plan created using DMPonline

Title: Risk of Emergent Inflammatory Bowel Disease Associated with Secukinumab and Traditional Systemic Therapies for Psoriasis or Psoriatic Arthritis

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Project abstract:

Psoriasis is a long-term, currently incurable, skin condition which can be life-ruining. Patients with psoriasis get thick red scaly plaques anywhere on the body, and often does affect parts of the skin visible to others, like the scalp and the hands. Fortunately, there are fantastic treatments available to patients with severe psoriasis now. The introduction of biologic therapies, which are complex medicines based on antibodies against overactive parts of the immune system in psoriasis, has radically transformed the way we can treat patients with psoriasis. Secukinumab is a very effective biologic therapy for psoriasis that was introduced in 2013. When it was tested in clinical trials, treatment with secukinumab in patients with psoriasis led to small numbers of new cases of inflammatory bowel disease, which are diseases that lead to inflammation of the gut and can be extremely severe, leading to radical surgery for bowel removal in up to 3 in 4 people with the condition. The problem with this data is that clinical trials are not representative of the overall population of patients with psoriasis. Patients recruited into trials are highly selected, and often a lot healthier than other patients with severe psoriasis. My project aims to use large US medical insurance claims data to investigate the real risk of secukinumab in causing inflammatory bowel disease, by comparing this drug to other medications used to treat severe psoriasis. The results from this study, the first analysis of its kind, will help patients and clinicians better understand this risk.

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Risk of Emergent Inflammatory Bowel Disease Associated with Secukinumab and Traditional Systemic Therapies for Psoriasis or Psoriatic Arthritis

Data Collection

What data will you collect or create?

None will be collected

How will the data be collected or created?

No data will be collected or created through this project. Existing data will be used.

Documentation and Metadata

What documentation and metadata will accompany the data?

Stata do files will be produced to managed the data.

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethical approval has been obtained for use of the data in Harvard Medical School.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

No data will be created and therefore there is no IPR issues.

Storage and Backup

How will the data be stored and backed up during the research?

Data will only be stored onto Harvard Medical School intranet systems, and no data will be taken out of the system apart from the aggregated results.

How will you manage access and security?

Data access will be granted through a research contract with Harvard Medical School. Data security will be ensured through access of data only on university computers. No data will be downloaded onto personal computers or portable data devices.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

No data will be preserved past one year of data access as per agreements with Harvard Medical School.

What is the long-term preservation plan for the dataset?

Access to the research dataset will only be provided for one year. The dataset is curated and managed through Harvard Medical School systems.

Data Sharing

How will you share the data?

No data will be sharing from this project apart from aggregated results, which will be shared through scientific manuscripts.

Are any restrictions on data sharing required?

No data sharing will be performed.

Responsibilities and Resources

Who will be responsible for data management?

The researcher (ZY)

What resources will you require to deliver your plan?

No additional resources will be required to deliver the data management plan.